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A Randomised Trial of Endovascular and Open Surgery for Ruptured Abdominal Aortic Aneurysm – Results of a Pilot Study and Lessons Learned for Future Studies

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Introduction. *EVAR has the potential to improve outcome after ruptured abdominal aortic aneurysm (AAA). Published series have been based upon selected populations.*
Methods. *An interim analysis of a single centre prospective randomised controlled trial comparing endovascular aneurysm repair (EVAR) with open aneurysm repair (OAR) in patients with ruptured AAA was performed. Patients who had a ruptured AAA and who were considered fit for open repair were randomised to EVAR or OAR after consent had been obtained. Those in the EVAR group had pre-operative spiral computed tomographic angiography (CTA). The primary endpoint was operative (30-day) mortality and secondary endpoints were moderate or severe operative complications, hospital stay and time between diagnosis and operation. A power study calculation required 100 patients to be recruited.*
Results. *Between September 2002 and December 2004, 103 patients were admitted with suspected ruptured AAA. Only 32 patients were recruited to the study. Of these, four patients died before receiving surgical treatment. On an intention to treat basis the 30-day mortality rate was 53% in the EVAR group and 53% in the OAR group. Moderate or severe operative complications occurred in 77% in the EVAR group and in 80% in the OAR group. Median total hospital stay in the EVAR group was 10 days (inter-quartile range 6–28) and 12 days (4–52) in the OAR group. Median time between diagnosis and operation was 75 minutes (64–126) in the EVAR group and 100 minutes (48–138) in the OAR group.*
Conclusions. *Despite the relative high operative mortality in the EVAR group, these preliminary results show that it is possible to recruit patients to a randomised trial of OAR and EVAR in patients with ruptured AAA. CT scanning does not delay treatment.*

Keywords: Abdominal aortic aneurysm; Ruptured aneurysm; Randomised controlled trial; EVAR; Open aneurysm repair.

Introduction

Endovascular aneurysm repair (EVAR) has become an accepted and widely performed technique for the management of elective abdominal aortic aneurysm (AAA). Recent multicentre randomised controlled trials have confirmed that it can be performed with reduced peri-operative morbidity and mortality compared with open repair.[1,2] Patients, who are critically ill with ruptured AAA, could be the most likely to benefit from a less invasive procedure. However, over a decade since it was first described, EVAR of ruptured AAA has not been widely adopted.[3]

Whilst early studies demonstrated the feasibility of EVAR of ruptured AAA they also identified issues surrounding the new technique notably aneurysm morphology, logistics and stent-graft requirements.[4,5]

Recent publications suggest these problems may have been surmounted. Refinements of the technique have shown EVAR can be performed with lower peri-operative morbidity and mortality than may have been expected with open repair.[6,7] The results of these studies may have been biased by patient selection. Currently, there is no level one evidence to support the widespread adoption of EVAR in an unselected population of patients who present with ruptured AAA.[8]

In order to test the hypothesis that EVAR can reduce the peri-operative mortality of ruptured AAA, a single centre prospective randomised controlled trial comparing EVAR with open repair of ruptured AAA was performed.

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Methods

This was a single centre randomised controlled trial performed on an intention-to-treat basis. The study received local ethics committee approval. In addition, the problems of informed consent were discussed at length by an independent ethics of clinical practice forum consisting of members of the Judiciary, religious representatives, members of the public, family practitioners and senior hospital doctors who were not vascular surgeons. Recruitment began in September 2002. Results presented include all patients recruited between 1st September 2002 and 31st December 2004.

Power calculations were based on the mortality rate for open aneurysm repair in our unit which was 50 percent. Interpolation of a pilot study in emergency EVAR in our unit suggested an expected outcome of 25% mortality rate for EVAR. It was thought that some 10% of patients randomized to EVAR might not be suitable and would require open repair. Of those, 5% could die. It was calculated that 100 patients had to be recruited to have a 90% power to show a statistically significant (5% chance of error) reduction in mortality rate to 25%.

Trial entry criteria were kept as broad as possible in order to encourage recruitment and reduce bias (Table 1). All patients admitted to the University Hospital, Nottingham with clinically suspected or radiologically confirmed rupture of an infra-renal abdominal aortic aneurysm that, in the opinion of the duty consultant vascular surgeon, would normally be treated with open repair were eligible.

Recruitment

There were several logistical and ethical hurdles that had to be addressed before recruitment could proceed.

As the level of endovascular experience varied between the five surgeons on the unit, the first requirement was that the surgeon and team available had sufficient expertise to offer EVAR, if not conventional OAR was offered.

Ethical issues also had a direct bearing on the recruitment, which occurred as follows: Since randomisation could result in open repair, only patients considered suitable for open repair of their ruptured aneurysm were randomised. In addition, because of potential concern that very unstable patients might be disadvantaged by the delay incurred during CT scanning, the surgeon could at their discretion not randomise patients and take them directly to the operating theatre for OAR.

Before a patient could be recruited, sufficient members of the EVAR team had to be present. The essential components of the team were a consultant vascular surgeon trained in EVAR and a radiographer familiar with the mobile image intensifier. Desirable, but not essential members of the team were a vascular radiologist and a junior surgeon to act as assistant.

According to the rules set by the ethics of clinical practice committee, verbal or written consent was taken after the clinical diagnosis of ruptured AAA had been made.[9] Patients were read a standard information card by the attending vascular surgeon and the consent process was witnessed by an unrelated healthcare professional. Randomisation was then performed from sealed opaque envelopes kept in the Accident and Emergency Department.

Any patients in whom there was diagnostic uncertainty had a CT scan. In these cases, entry to the study and randomisation took place at the time of CT diagnosis. The surgeons were blinded to the dimensions of the patient's aorta until randomisation had taken place. This was to avoid bias if the CT subsequently showed an aneurysm that was not suitable for EVAR, when the surgeons might not have offered trial entry.

Patients randomised to open repair were transferred directly to the operating theatre according to local practice. Those randomised to EVAR were transferred for aortic measurement using computerised tomography (CT) scanning prior to transfer to the operating theatre (Fig. 1). Those who had a diagnostic CT were transferred to the operating theatre.

Aneurysm morphology was assessed using spiral CTA on a spiral unit following the standard local protocol. Scans were performed from upper L1 to the symphysis pubis to ensure coverage of the aneurysm from the visceral aorta to the external iliac arteries, with 5 mm collimation, 3 mm index, 1.5:1 pitch, with exposure factors of 120 kVp and 225 mA. Contrast was injected with a pump injection of 50 ml Omnipaque 300 with a typical delay of 20 seconds, at a rate of 3 ml per second. No medication was given

Table 1. Patient exclusion criteria

Exclusion criteria
No endovascular team available
Full selection of emergency stent-grafts not available
Age < 50 years
Inability to give verbal or written consent
Unconscious patient
Allergy to radiological contrast, stainless steel or polyester
Severe co morbidity that would preclude intensive care treatment following open repair
Previous endovascular AAA repair
Women of child bearing potential not taking contraception
Pregnant and lactating women

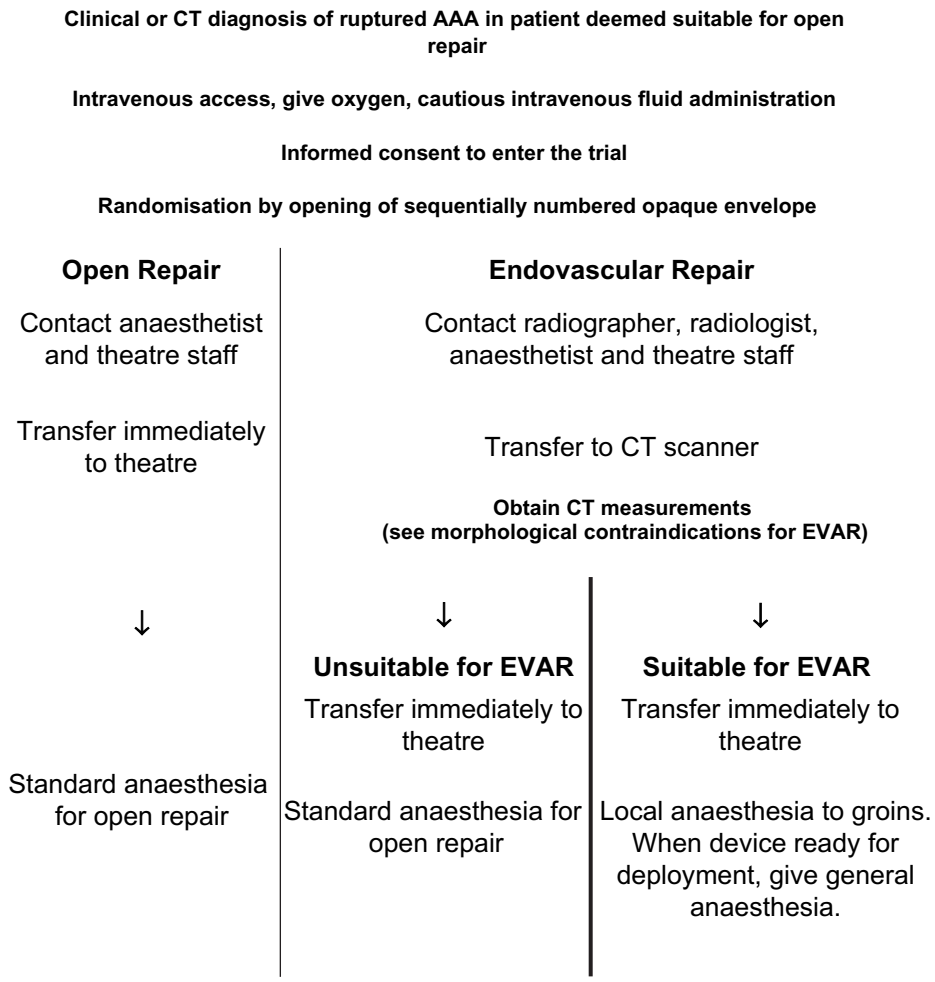

Fig. 1. Flow diagram of patients entered in to the trial.

to reduce contrast-induced nephropathy. The contrast load was less than the standard volume for elective scans as only 3 measurements were required for graft planning: diameter of aortic neck, length of aortic neck and iliac artery diameters. Patients were deemed suitable for EVAR if, in the opinion of the operating surgeon, they could perform the repair (Table 2). The department had experience of some 350 elective and 35 emergency EVARs at the start of the study. Neck diameters of 32 mm or less and neck lengths of 5 mm or more were deemed suitable as the patients were in a different situation to those who required elective repair. It was accepted that some patients might need secondary interventions at a later date but the role of the procedure was to arrest haemorrhage and allow resuscitation to a near normal physiological state.

The endovascular procedure was performed in a dedicated vascular operating theatre using a Siremobil 2000 image intensifier (Siemens, Erlangen, Germany) with digital subtraction angiography facilities. Local anaesthetic was infiltrated in both groins (1% lidocaine). Oblique or vertical groin incisions were used and the stent-graft inserted via the

Table 2. Morphological exclusion criteria

Absolute contra-indications	Relative contraindications
No evidence of aneurysm rupture	Proximal neck length <10 mm
Juxta-renal aneurysm	Excessive thrombus in the proximal neck
Neck diameter >32 mm	Common iliac artery length <25 mm
External iliac artery diameter <6 mm	Heavily calcified iliac arteries

common femoral artery. General anaesthesia was commenced prior to deployment of the stent-graft as the pain from temporary limb ischaemia had been found to make patients restless and unco-operative. Most patients were systemically heparinised. All patients received a two-piece aortouniiliac stent-graft made with Gianturco stents with an uncovered suprarenal component. At each procedure, the surgeon had a choice of proximal stent diameters of 34 mm, 30 mm, 26 mm and 22 mm. The distal (iliac) limbs available were 24 mm, 20 mm, 16 mm and 12 mm. An occluding device was used in the contralateral common iliac artery (Zip plug - Cook Europe, Copenhagen, Denmark or Endomed, Arizona, USA).[5] After deployment of the stent-graft and exclusion of the aneurysm, a femoro-femoral cross-over graft was performed (Gelsoft, Vascutek, Renfrewshire, UK). A consultant vascular surgeon did all procedures. A consultant radiologist was sometimes involved in assessing the CTs.

A policy of permissive hypotension was started on admission in all cases until the surgeon informed the anaesthetic team that the aneurysm had been excluded from the circulation. Fluid resuscitation was then instituted. Intra-aortic balloon insertion was not used. Patients were transferred to the vascular ward, high dependency unit or intensive care unit, depending on their status at the end of the procedure.

Follow up of survivors of EVAR involved a postoperative duplex ultrasound to exclude a large endoleak followed by A CT scan prior to discharge from hospital.

Open repair was performed transperitoneally either by midline or transverse incisions according to the operating surgeon's preferred method. All cases were under general anaesthesia. The aorta was clamped below the renal arteries. Patients were not heparinised. An inlay technique was used in all patients and grafts were gelatin-coated polyester (Gelseal or Gelsoft, Vascutek, Renfrewshire, UK). A consultant vascular surgeon performed all operations. Patients were transferred to the intensive care unit for standard postoperative care.

The results of a planned interim analysis are shown below:

All results are expressed as medians with interquartile ranges in parenthesis. Peri-operative mortality was defined as 30-day or in-hospital mortality. Mortality was assessed both on an intention to treat basis and on peri-operative mortality of each procedure in isolation.

Outcomes were classified according to the Ad Hoc Committee on Reporting Standards, Society for Vascular Surgery and North American Chapter, International Society for Cardiovascular Surgery.[10]

Patients

Between 1st September 2002 and 31st December 2004, some 103 patients were diagnosed with a ruptured aortic aneurysm (Fig. 2). Seventy-one patients admitted with a diagnosis of ruptured AAA were not recruited. Of these, 55 were either moribund or refused surgical intervention. The essential components of the team were not available for eight patients and they went on to have open repair. Some six patients were thought to be 'too haemodynamically unstable' for CT scan. They were taken to theatre for open repair and all died within 30 days. Two patients were not thought suitable for open repair and were not recruited. They had EVAR done on compassionate grounds. One died from respiratory failure following an anaesthetic complication. The other was discharged home.

Some 32 patients were recruited to the study, 17 were randomized to open repair (Fig. 2). All patients randomized in the trial were subsequently discovered to have ruptured AAA at CT or laparotomy.

Patient characteristics in the two treatment arms were similar (Table 3.) A total of five patients undergoing EVAR and six undergoing open repair were admitted with a systolic blood pressure less than 100 mmHg (unstable patients).

The median time between clinical diagnosis and operation was 75 minutes (inter-quartile range 64–126) in the EVAR group and 100 minutes (46–138) in the OAR group (Table 4). The operative times and fluid replacements are given in Table 5.

Outcome of Patients Randomized to Open Repair

Of the 17 patients randomized to OAR three died before they could reach theatre. Of the 14 in whom the operation was commenced, two died on table and 12 survived the operation. A further four died in the peri-operative period. This gives a mortality of 9/17 (53%) on an intention-to-treat by conventional open aneurysm repair. The peri-operative mortality of those surviving to reach theatre to undergo open repair was 6/14 (43%).

In the OAR group, one patient was converted to an axillo-bifemoral graft due to the presence of an unsuitable proximal aortic neck. He survived the operation but developed respiratory failure from which he recovered. He was discharged home with a low-grade graft infection treated with antibiotics.

In the OAR group, there were three inadvertent injuries intra-operatively including damage to the renal and gonadal veins and renal artery occlusion. Three patients required femoral embolectomy, for distal

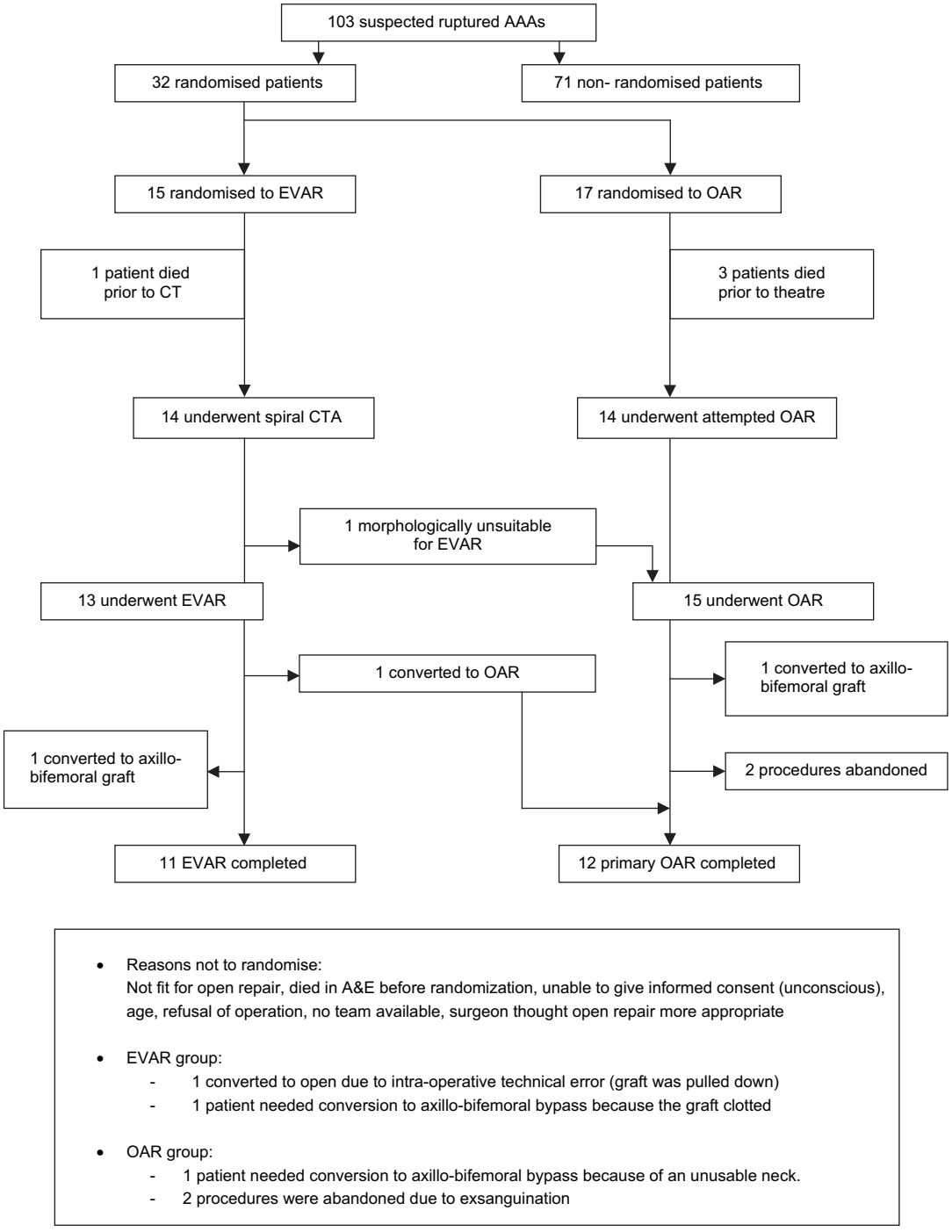

Fig. 2. CONSORT diagram of outcome of patients admitted with a suspected diagnosis of ruptured AAA during the trial period.

embolisation. One patient required laparostomy- he had presented with a two week history of abdominal pain and had such a large haematoma that the operating surgeon felt primary closure would have resulted in abdominal compartment syndrome. There were also three re-operations within the first twenty-four hours for bleeding related to the aneurysm repair.

Outcome of Patients Randomized to EVAR

Fifteen patients were randomized to EVAR. One died during transfer to CT and one underwent open repair because of unsuitable morphology detected in CT – the aneurysm neck was too wide for the available devices. He underwent open repair from which he made

Table 3. Baseline patient characteristics

Patient demographics	EVAR	OAR
	Median (inter-quartile range), (number)	
Age	74 (68.8–79.5)	80 (73.8–83.8)
Male	11	13
Ischaemic heart disease	3	5
Chronic obstructive airways disease	0	3
Peripheral vascular disease	1	2
Renal disease	1	2
Hypertension	5	8
Active smoker	4	6
Ex-smoker	8	3
Known AAA	3	7
Abdominal/back pain	6	9
Collapse	7	6
Loss of consciousness	2	2
Symptom duration (minutes)	210 (110–1440)	590 (83–2520)
Systolic blood pressure on arrival A + E (mm Hg)	119 (93–155)	120 (85–138)
Systolic blood pressure on arrival theatre (mm Hg)	110 (96–140)	120 (100–134)
Crystalloid given in A + E (ml)	625 (0–1500)	750 (0–1000)
Colloid solution given in A + E (ml)	100 (0–1000)	250 (0–1000)
Haemoglobin on arrival in A + E (g/dl)	10.9 (8.2–13.2)	11.3 (10.3–13.1)
Haematocrit	0.33 (0.25–0.4)	0.35 (0.32–0.39)
White cell count (109/l)	13.0 (10.7–16.1)	11.5 (8.6–15.1)
Platelets (109/l)	182 (144–285)	203 (153–277)
Urea (mmol/l)	7.1 (5.8–9.2)	7.6 (7.1–10.7)
Creatinine (umol/l)	110 (96–175)	133 (116–152)

a good recovery. He was discharged from hospital, the only complication being urinary retention.

Thirteen patients had attempted EVAR. Two required conversion to an open procedure. One patient was converted to open repair because of a technical error (the top stent was caught in the delivery system by the operating surgeon). This patient died 10 days post-operatively from a combination of respiratory failure, stroke and myocardial infarction. Another patient was converted to an axillo-bifemoral graft because of a stent-graft thrombosis. The thrombosis occurred because of a combination of a stenosis in the common iliac artery and a surgical error in not withdrawing the delivery system into the external iliac artery to allow flow in to the internal iliac artery. This patient survived. All subsequent patients who had EVAR were given systemic heparin (3000 to 5000 units) before graft insertion as is the standard practice with elective repair.

Table 4. Pre-operative CT derived aneurysm measurements in patients who had EVAR

Morphological variable	Measurement (mm) Median (inter-quartile range)
Maximum AAA diameter	85 (80–100)
Supra-renal diameter	28 (25–31)
Neck length[a]	15 (9–22)
Neck diameter	26 (23–29)
Renal artery – aortic bifurcation	131 (126–147)
Right common iliac artery length	48 (38–55)
Left common iliac artery length	50 (38–53)
Right common iliac artery diameter	16 (13–20)
Left common iliac artery diameter	16 (14–21)
Right external iliac artery diameter	10 (8–11)
Left external iliac artery diameter	10 (8–11)

*Three patients had free intra-peritoneal rupture on CT.
[a] One patient with short neck deemed unsuitable for EVAR and underwent OAR.

A total of 11 EVARs were successfully completed. A further six patients died peri-operatively. No patients were diagnosed with intra-abdominal compartment syndrome. On an intention to treat basis, 8/15 (53%) of patients randomized to EVAR died. The operative mortality in those who had a completed EVAR procedure was 6/13 (46%).

In the EVAR group, 77% of patients had moderate or severe complications compared with 80% in the OAR group (Table 6). The median total hospital stay in the EVAR group was 10 days (6–28) compared with 12 in OAR (4–52).

More patients in the EVAR group suffered severe renal complications (6 (55%) versus 1 (8%) in OAR, $p = 0.02$).

In the patients undergoing EVAR, there were two additional endovascular interventions and two open. A Palmaz stent (Johnson and Johnson) was deployed intra-operatively for type 1 endoleak and in another patient a Palmaz stent was used to seal a proximal (type 1) endoleak detected by postoperative investigations. The two conversions to open repair are noted above.

Discussion

This is the first study to report a randomized trial between EVAR and OAR in patients who present with a ruptured AAA.

The study shows that it is possible to perform an ethical randomized study of EVAR compared with open repair for ruptured AAA.

Concerns that CT scanning prior to surgery causes detriment to the patient appear to be misplaced. Patients who were so unstable that the surgeon deemed CT scanning unethical did badly with open repair. These patients may even be those who have most to gain from endovascular repair. The time interval between arrival and operation was similar in the two groups with the open repair having a slightly longer delay. This may be a chance event or reflect that the open repair group had a higher proportion of patients

in whom there was diagnostic delay. Provided CT scan can be performed promptly it need not cause unnecessary delay or detriment.

The finding that mortality rates were comparable in open and endovascular groups was disappointing and at variance with our own previous experience of endovascular repair in selected rupture cases and those in the literature. This may reflect that selected case series invariably produce better results than randomised controlled studies and provide support for a further multicentre study with larger numbers of patients. Certainly given that there was not a clear superiority of one technique over the other it continues to be ethical to randomize patients between the two techniques. There may be other contributory factors including patient selection and the experience of the team available.

The most commonly used proximal graft size was 34 mm in diameter. This confirms previous studies that ruptured aneurysms are often associated with large diameter necks.[11] It was possible to successfully exclude aneurysms with angulated and short necks. In an elective situation, this would not have been attempted. When faced with a patient about to die, the study protocol allowed the vascular surgeon to use EVAR if they felt there was a reasonable chance of successful exclusion of the aneurysm. As was noted in one patient, pushing the anatomical limits of EVAR for rupture resulted in two proximal endoleaks. Both of these were treated by endovascular means. This analysis has shown that the measurement guidelines for elective EVAR can be ignored in patients with ruptures. If there are problems with the device then a secondary intervention can be done when the patient is physiologically better than at the time of presentation.

One of the disadvantages of the aortouniiliac system is that all patients needed general anaesthesia. Although guide-wire placement and graft delivery could be done under local anaesthesia in the groin, the ischaemic pain during the femoro-femoral crossover was too painful for most patients. In the study almost two-thirds of EVAR patients consequently suffered a severe respiratory complication. Some centres have used bifurcated stent-grafts under local anaesthesia with encouraging results.[7] The disadvantage of that system is the need for a potentially difficult catheterisation in a patient who continues to bleed through the contralateral stump. Some refinement of technique may be helpful in these situations. The use of an occluding balloon for bifurcated grafts may also be an important adjunct.[12] Another disadvantage in using a bifurcated system may be the need to have a large stock of main body systems.

Table 5. Fluid replacement and operative times

Procedural characteristics	EVAR ($N = 13$)	OAR ($N = 15$)	P value
Duration in theatre (mins)[a]	160 (150–234)	150 (141–204)	0.34
Estimated blood loss (ml)	200 (163–450)	2100 (1150–3985)	0.004
Blood products transfused			
Autologous blood (ml)	0	222 (0–500)	0.004
Homologous blood (units)	3.0 (0–5)	6.0 (4–9)	0.02
Fresh Frozen Plasma (units)	0 (0–0.5)	0 (0–2)	0.12
Platelets (units)	0	0	–
Intravenous fluid administration			
Crystalloids (ml)	2000 (1375–3125)	2000 (1000–3000)	0.39
Colloids (ml)	1000 (500–1500	1750 (1000–2600)	0.01

[a] Duration in theatre was taken from the start of the anaesthetic to the patient exiting the operating theatre.

The only significant finding was EVAR resulted in less blood loss and a statistically significant reduction in blood product usage (Table 5). This is unlikely to be sufficient evidence to recommend that EVAR is better than OAR when mortality remains similar.

Units, which decide to adopt EVAR for ruptured AAA, must be aware of the need for renal support post-operatively. A large proportion of patients developed renal failure in the endovascular arm of the trial. Potential causes may be atherosclerotic embolisation or contrast nephropathy. The volume of contrast given

Table 6. Post-operative complications

Systemic complications	EVAR ($N = 11$)	OAR ($N = 12$)
	Number	
Renal		
Moderate	1	4
Severe	6	1
Pulmonary		
Moderate	4	1
Severe	7	6
Cardiac		
Moderate	5	6
Severe	0	1
Cerebrovascular		
Moderate	0	0
Severe	1	0
Coagulopathy		
Moderate	1	1
Severe	1	1
Other		
Moderate	2	4
Severe	1	2

Complications classified according to the reporting standards of the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/International Society for Cardiovascular Surgery.[10]
Patients who died intra-operatively are excluded from analysis.

to these patients was considerably greater than in an elective situation. In addition to the contrast given at CT (50 ml) they also had a median of 150 ml intraoperatively. Large contrast volumes and intravascular depletion are recognised risk factors for the development of contrast-induced nephropathy.[13] Difficult aneurysm morphology, requiring very precise deployment of the stent-graft was a contributory factor to the large volumes of contrast used. This was compounded by the presence of retroperitoneal haematoma and a low cardiac output, both of which deteriorate angiographic images. In an attempt to reduce renal injury, the CT protocol had been changed to a reduced volume and diluted contrast is given in theatre. Another solution to renal complications may be to provide haemofiltration for all patients following EVAR.[14] The use of N-acetyl cysteine as a free radical scavenger relies upon pre-contrast administration and is therefore unlikely to be beneficial. There is some evidence that NaHCO3 infusions reduce renal problems- it may be worth using these infusions in the future.

The study shows that nearly 47% of patients admitted with a ruptured AAA are not deemed suitable for open aneurysm repair. It also shows that in an unselected population, a trial with 100 patients is unlikely to be sufficiently powerful to show a difference in the 2 techniques. Much larger studies will be required to obtain level one evidence. This study has been suspended but we believe provides useful information for those considering similar studies in future.

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